

TESTIMONY OF ANGELA TREPANIER, CGC, Assistant Professor, Director
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National Society of Genetic Counselors
before the
STATE OF MICHIGAN HOUSE OF REPRESENTATIVES
HEALTH POLICY COMMITTEE

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Chairman Marleau, Vice-Chairman Robertson and distinguished Members; I am Angela Trepanier, a Certified Genetic Counselor, from Detroit. I am a faculty member and director of the genetic counseling graduate program at the Wayne State University School of Medicine. I am also a member of the Michigan Association of Genetic Counselors and past president of the National Society of Genetic Counselors (NSGC). On behalf of Michigan Genetic Counselors we want to thank Senator Emmons for introducing **Senate Bill 935**. I appreciate the opportunity to testify in favor of this important legislation that would provide licensure for certified genetic counselors in Michigan.

Who are genetic counselors?

Genetic counselors are healthcare providers with significant training and expertise in human and medical genetics, patient education, and psychosocial counseling, obtained through a 2-year Masters level program. Most students enter the field from a variety of disciplines including biology, genetics, psychology, and public health. There are 32 accredited graduate programs in the United States including two in Michigan, housed at the University of Michigan and at Wayne State University.

Genetic counselors are part of a health care team providing information and support to individuals and families concerned about risk of genetic disorders.
Genetic counselors:

- Collect and interpret family and medical histories,
- Identify individuals and families at risk of genetic conditions
- Explain inheritance and natural history
- Quantify chance of occurrence and recurrence
- Review available testing options
- Provide informed consent for genetic testing
- Discuss management, prevention, and research opportunities
- Serve as patient advocates and refer individuals and families to community or state support services as appropriate

Genetic counselors are employed in a wide range of clinical care, academic, laboratory, research, and biotechnology settings. Within Michigan there are approximately 100 genetic counselors, a majority of whom provide direct patient care in a variety of specialties such as Obstetrics, Oncology, Pediatrics, Neurology, Cardiology, Ophthalmology, and pre-implantation genetic diagnosis.

There are several genetic counselors working for genetic testing laboratories. In addition, there are a number of genetic counselors working for the Michigan Department of Community Health on public health genomics programs including newborn screening follow up and chronic disease genomics. In fact, Michigan is a model state in terms of advancing public health genomics initiatives.

Why do we need genetic counseling licensure?

SB 935 is extremely important as the bill would help protect the public from potential harms that may result from this occupation remaining unregulated. Documented harms caused by untrained individuals attempting to provide genetic counseling include:

- Misinformation regarding genetic risk or lack of risk;
- Misunderstanding of the implications of genetic information such as family history or test results, which can lead to:
 - unnecessary medical treatment and/or surgery
 - lack of prevention or disease monitoring strategies
 - irreversible management decisions
 - Avoidable fear, anxiety and guilt
- Lack of informed consent prior to presymptomatic or predispositional testing (state law)
- Inappropriately undertaking costly genetic testing

The availability of genetic and genomic testing services is growing rapidly. The National Institutes of Health Genetic Testing Registry lists genetic tests for more than 4400 different diseases. Not only are there more tests, but the complexity of testing is changing. Experiences with whole exome and genome sequencing as well as next generation sequencing panels has shown us that there are a myriad of issues that have to be considered when you look at all of a person's genetic information. For instance, what do you do when you incidentally identify risk for an adult onset condition in a child having full exome sequencing to identify the cause of his multiple birth defects? Or, what do you do when a clinically available SNP-based microarray test, which tests for extra or missing genetic information and is routinely ordered in individuals with mental retardation and birth defects also identifies that the child is the product of an incestuous relationship?

To quote the Secretary's Advisory Committee on Genetics, Health and Society's 2011 Executive Summary on Genetics Education and Training,

"The growing integration of genetics and genomics findings into mainstream medicine and the emergence of direct-to-consumer genetic testing amplify the need for understanding risk assessment, multi-gene and genomic diagnostics, genetic-based treatment, and effective strategies in communicating genetic test results to patients and consumers. However, health care professionals, the public health workforce, patients and consumers are challenged to keep pace with this dynamic and rapidly evolving field."

Genetic counselors, with their specialized training, are ideally suited to work hand-in hand with physicians and health care providers to ensure the delivery of high quality, up-to-date genomics services and to make sure that the patients utilizing these services are adequately informed. As such, they are key players in appropriately integrating genomics into health care and also in avoiding the significant harm that can occur when genetic risk is not identified or when a patient is not properly counseled before genetic testing is done.

In addition, genetic counselors provide services that are cost-effective. We assure tests are utilized appropriately. Many health care providers often request unnecessary testing or incorrect tests increasing the cost of health care. Non-genetics health care professionals have also been demonstrated to underestimate patients' genetic risks because of ineffective family history evaluation. For many genetic conditions, 50% of first degree relatives (siblings, parents, children) of a person with a genetic mutation will also carry a mutation and are at risk to manifest the disease or transmit the mutation. Identifying those who carry a mutation offers the opportunity for preventive screening and treatment, thus lowering the chance of disease manifestations. Moreover, identifying those family members who do *not* carry a mutation eliminates the need for expensive clinical follow-up.

Genomics is changing rapidly and genetic counselors are key players in appropriately and effectively integrating genomic applications into health care. Clinicians and patients need to know that the genetic counselors they work with/see are adequately trained and up-to-date on genomic information. We urge you to enact this legislation as it would establish requirements for the licensure of genetic counselors ensuring minimum standards for individuals in terms of academic achievement, clinical experience, and skills necessary to deliver high quality genetic counseling services. Currently in Michigan there is no legal standard for who can represent themselves as genetic counselors. As the field of medical genetics grows, there is and will continue to be a need to provide the citizens of Michigan with accurate information regarding their genetic risks and results of genetic tests. At present, there is no mechanism that assures citizens that the individual who is providing this information is qualified to do so. In a climate where direct-to-consumer genetic testing via internet companies is available and where the complexity of genomic tests is increasing, the citizens of Michigan need to have access to professionals who have been deemed qualified by the state to help them understand their potential genetic risks.

Additionally, there is no way for employers to assure they are hiring individuals who have the appropriate training and education to provide genetic counseling services or that would prohibit unskilled individuals from using the title of genetic counselor.

This is also important to Michigan in terms of maintaining a high quality genetic counseling workforce. As I previously stated, there are 2 genetic counseling graduate programs in Michigan and we graduate approximately 12 students per year. Currently, about 45% of my graduates seek employment in Michigan and make up almost a quarter of the state's workforce. To date, 19 states, including our closest neighbors, Ohio, Indiana, Illinois, and Pennsylvania, have passed licensure legislation. Students may preferentially select to attend programs in states with licensed genetic counselors. Even those who train here may seek employment outside of Michigan in states with licensure. We may also have a hard time attracting new graduates from outside the state to practice here or may not get the same caliber of graduates as states with licensure get. These circumstances would place our state at a disadvantage compared to others and it could result in a loss of revenue and tax base. In addition, it could decrease patient access to the specialized health care services that genetic counselors provide.

In conclusion, the Michigan Association of Genetic Counselors is hopeful that the committee will work with Senator Emmons to enact genetic counseling licensure that will ensure the people of Michigan receive quality genetic counselor services. We believe the people of Michigan will be well served. We thank the Chairman and this committee for your attention to this important issue, and we offer ourselves as a resource as you move forward.

"Genetic counseling is a critically important component of the appropriate use and integration of genetic tests and services"

Report of the Secretary's Advisory Committee on Genetics, Health, and Society. 2006



Genetic Counselors

Uniquely qualified and solely dedicated to providing competent genetic counseling services¹

Genetic
counseling is
the process of
helping people
understand
and adapt to
the medical,
psychological,
and familial
implications of
genetic
contributions
to disease.²

Genetic counselors are health care providers uniquely trained in Master's degree programs to provide quality genetic counseling services. Genetic counselors are certified by the American Board of Genetic Counseling.

In health care settings, genetic counselors are tasked with:

- Eliciting and interpreting medical and family histories.
- Calculating the risk of occurrence or recurrence of a genetic condition.
- Imparting clear, accurate and comprehensive information regarding medical conditions with a genetic component, including risks, symptoms, screening and treatment options as well as testing options to patients and healthcare providers.
- Providing psychosocial support to individuals and families coping with a genetic condition.

Genetic counselors work closely with individuals and families to:

- Determine the appropriateness of pursuing genetic technologies.
- Facilitate informed decision-making.
- Communicate with the family, laboratories and other healthcare providers.
- Promote screening and preventative care to minimize health risks.

Genetic counselors:

- Recognize and respond to ethical and moral dilemmas.
- Identify factors that promote or hinder client autonomy.
- Understand issues surrounding privacy, informed consent, confidentiality, and real or potential discrimination.

Each year, thousands of Michigan residents benefit from the services provided by genetic counselors.

- 1 in every 20 babies is born with a birth defect³
- 20-30% of all infant deaths is due to genetic disorders⁴
- 1 in every 9 pediatric hospital admissions is for a child with genetic disorder⁵
- 1 in every 8 adult hospital admissions is for a genetic cause⁶
- 50% of intellectual disability has a genetic basis⁷
- 15% of all cancer has an inherited susceptibility⁸
- 10% of chronic disease (heart, diabetes, arthritis) has a significant genetic component⁹

Genetic counselors work in various health care settings in Michigan, including universities, industry, public and private health care settings.

Areas of practice include:

- Pediatric Genetics
- Cancer Genetics
- Neurogenetics
- Reproductive Genetics
- Infertility Clinics
- Other specialty Clinics

To find a genetic counselor, go to www.nsgc.org or www.abgc.net.

To view the centers where genetic counselors work, visit www.migeneticsconnection.org.

Now is the Time to License Michigan Genetic Counselors

Genetic Counselor Licensure will provide Michigan citizens:

- **Protection from harm of receiving inaccurate information about genetic risks from individuals who do not meet minimum education and certification standards.**
 - Numerous cases of physical, psychological, or financial harm due to the inappropriate use or interpretation of genetic information in Michigan have been described.¹
 - Errors in care may be inevitable, but regulating providers through competency guidelines should reduce the frequency.
 - Approximately 30% of non-genetics health care providers misinterpret the results of genetic tests that they order on their patients.² These errors in interpretation can have a significant impact on patients and their family members.
- **Cost savings of healthcare dollars via accurate testing on appropriate individuals.**
 - Healthcare providers without training in genetics often order more expensive genetic testing than is indicated, amounting to unnecessary health care expenditures.³
- **Assurance that minimum education, continuing education, and certification standards have been met by individuals using the title of genetic counselor.**
 - Genetic counselors hold advanced degrees and are uniquely trained to provide their services.
 - The public and some healthcare providers are generally unaware of the minimal standards for formally trained genetic counselors. In fact, patients report receiving services from what they originally believed to be genetics experts, when in fact the providers of these services had very limited, if any, formal genetics training.
 - The growing availability of direct-to-consumer genetic testing makes the urgency of ensuring the availability and recognition of quality genetic counseling services to patients in Michigan even greater.⁴
 - Human genetics is advancing rapidly, making continuing education critical. In 2014, genetic testing is available for over 4,400 diseases, an increase of over 3,000 diseases over the last 10 years. In the absence of regulation, compliance for important continuing education may be deficient since adherence to professional recommendations is otherwise voluntary and not required to work as a genetic counselor.
- **Reassurance that the quality of care in the state of Michigan is comparable to that of neighboring states.**
 - Some of our nearest neighbors, Ohio, Illinois, Indiana, and Pennsylvania have enacted laws for genetic counseling licensure. Ohio and Wisconsin are actively pursuing similar legislation.
 - Without licensure, individuals without the appropriate credentials could provide genetic counseling and therefore decrease the quality of the service in Michigan as compared to neighboring states with regulation.
- **A mechanism to report, investigate, and sanction claims of incompetent, unethical, and/or unlawful behavior of a genetic counselor.**
 - In the absence of regulation, there are no professional consequences for practicing outside of defined guidelines. Without regulation, incompetent genetic counselors can continue practicing, leaving families in Michigan vulnerable.
- **Guarantee that the state is working to train and retain highly educated health care professionals.**
 - The state of Michigan is home to two graduate training programs in genetic counseling. Graduates of these programs are in high demand and consider the availability of licensure in a state when seeking employment.

References:

1. Brierley K, et al. Errors in Delivery of Cancer Genetics Services: Implications for Practice. *Conn Medicine*. 2010;74(7):413-425.
2. Giardiello FM, et al. The use of interpretation of commercial APC gene testing for familial adenomatous polyposis. *NEJM*. 1997;336(12):823-7.
3. Plon SE, et al. Genetic testing and cancer risk management recommendations by physicians for at-risk relatives. *Genet Med*. 2011;13(2):148-54.
4. U.S. Government Accountability Office (GAO). GAO-10-847T. <http://www.gao.gov/products/GAO-10-847T>. Updated July 22, 2010.



Genetic counselors are the health professionals specifically trained to address the complex issues associated with genetic disease.
